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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,417	10/31/2003	Shivkumar Mahadevan	VTN 5023	2097

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EXAMINER	
DRODGE, JOSEPH W	
ART UNIT	**PAPER NUMBER**
1723	

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/699,417	MAHADEVAN ET AL.	
	Examiner	Art Unit	
	Joseph W. Drodge	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13 and 15-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4,10,11,13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bawa et al patent 6,071,439, taken in view of one or more of the group of patents encompassing Nicholson et al patent 5,760,100, and Spinelli et al patents 5,371,147, 5,019,628 or 4,810,756, and if necessary, in view of Pilat et al

patent 2,188,013. Rejections based on formerly applied Kunzler have been dropped, and teachings of Maiden are deemed merely cumulative and no longer applied.

The claimed term "silicone-containing monomer" has been interpreted to actually encompass copolymers or oligomers containing multiple polymerizable groups and plural monomers or monomeric groups and to encompass completed intraocular lenses and other medical devices comprised of such "monomer" as discussed on page 2, lines 1-18, especially lines 14-18, and page 4, lines 23-27 of the Instant Specification.

Bawa et al disclose removal of impurities from manufacture of silicone-containing polymers and other polymers used in the manufacture of contact lenses by ***optionally plural steps or stages of*** solvent extraction with carbon dioxide in the supercritical state (column 1, line 60-column 2, lines 58). The extraction may be incorporated into any manufacturing step of the process of making the contact lenses (column 4, lines 23-32 and 62-68 and column 5, lines 13-16). The extraction is conducted under conditions of high temperature and high pressure, hence high density, in a closed chamber (column 7, lines 8-20), and afterwards purged when densities and pressures are suggested as returning to lower ambient conditions. ***Bawa discloses the contact lens materials being formed from a mixture of monomers including methacrylic acids and acrylic acids (column 3, lines 4-32) and also discloses that the contact lens materials include a not fully polymerized material that includes unreacted mixtures of monomers and oligomers, which also comprise impurities to be removed.***

Since there may optionally be several stages or steps of supercritical fluid solvent extraction (SCFE) required (column 4, lines 30-32 and Example 3), it is inferred that individual stages of the SCFE treatment result in phases containing both polymeric product and residual monomer(s) and other phases containing other impurities.

The claims all differ from Bawa et al in the particular silicone monomers and recited. Generally, various acrylic star monomers are claimed. However, Bawa et al disclose applying of the process to any conventional silicone monomers (column 3, lines 4-49) or to any lens-forming material (column 5, lines 3-13. Each of the Spinelli '756 , '628 and '147 patents and Nicholson teach employ of the recited acrylic star monomers and co-polymers in the manufacture of contact lenses (see the respective Summary of the Invention portions of texts regarding properties of the particular monomers). It would have been obvious to one of ordinary skill in the art to have selected the claimed acrylic star monomers taught by Spinelli '756, '628, or '147 or Nicholson, in the manufacture of the contact lenses of Bawa et al, to result in contact lens products having favorable characteristics such as improved oxygen permeability, toughness and strength.

The claims may optionally be considered to further differ in requiring the separation of two phases resulting from the solvent extraction to explicitly be caused by a lowering of density of the extractant. However, Pilat teaches to separate impurities from high molecular weight oily or other petrochemical or hydrocarbon mixtures by carbon dioxide so as to lower the density of the mixture to separate the mixture into two

liquid phases (page 1 from line 36 of column 1 to line 25 of column 2), with the impurities further separated into separate fractions by varying the pressures and temperatures, and hence the densities of the extraction in a series of sequential stages (page 2 from line 45 of column 1 to line 17 of column 2). If necessary, it would have been further obvious to one of ordinary skill in the art to have operated the Bawa et al solvent extraction process by effecting separation of purified silicone polymer from the undesired impurities, as taught by Pilat, to fractionate the varied, different contaminants of the mixture being separated, so as to result in a more complete separation and purification of the polymeric mixture.

For compositions containing the particular siloxane monomers of claims 16 and 17, see in particular Nicholson at columns 28,36 and 38, especially column 28, lines 27-52, which depicts siloxane monomers as imparting especially high oxygen permeability to the contact lenses being manufactured.

Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bawa et al patent 6,071,439 taken in view of one or more of the group of patents encompassing Nicholson et al patent 5,760,100, and Spinelli et al patents 5,371,147, 5,019,628 or 4,810,756 as applied to claim 1 above, and further in view of Pilat et al patent 2,188,013.

Claims 5-9 further differ in requiring the solvent extraction to be conducted in two or more stages with the density of the supercritical carbon dioxide being lowered in second and subsequent stages. However, Pilat teaches to separate impurities from

high molecular weight oily or other petrochemical or hydrocarbon mixtures by carbon dioxide so as to lower the density of the mixture to separate the mixture into two liquid phases (page 1 from line 36 of column 1 to line 25 of column 2), with the impurities further separated into separate fractions by varying the pressures and temperatures, and hence the densities of the extraction in a series of sequential stages (page 2 from line 45 of column 1 to line 17 of column 2). It would have been further obvious to one of ordinary skill in the art to have operated the Bawa et al solvent extraction process in successive stages having varied temperatures, pressures and densities, as taught by Pilat, to fractionate the varied, different contaminants of the mixture being separated to result in a more complete separation and purification of the polymeric mixture.

Applicant's arguments filed on 25 October 2006 have been fully considered but they are not persuasive. It is argued that the references do not disclose or suggest that SCFE is used to purify silicone-containing monomers instead of articles containing polymers/polymerized materials. ***It is submitted that in the primary Bawa reference process, the different stages of SCFE concern contact of SCFE with a mixture of both polymeric product and un-reacted monomers and oligomers (Bawa at column 3, lines 4-32 and column 4, lines 30-32 and Example 3). Again, it is noted that Kunzler is no longer applied against the claims.***

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

December 4, 2006

Joseph Drodge
Primary Examiner